we don't have enough masses to submit on our accreditation and we have to struggle to get it because if I can see on ultrasound, I'm going to do it on ultrasound.

So I don't believe that there'll be a competition between if stereo is regulated and people can't do stereo, that they're going to take the patient and do an ultrasound guided biopsy. If they're going to that, they're probably going to do the patient a favor. Because if you're doing a stereo when you could do an ultrasound, you're not doing it the easiest way.

The concern that Dr. Finder raised that people who can't do stereo will then take the patient to open biopsy, I'm concerned about that because I wouldn't want to see things go in that direction because the minimally-invasive technique I do think is better for women.

DR. BARR: Does anyone have any, because I know Congress will ask us this, thoughts or ideas or even information about we did see a certain percentage of the population drop out when

mammography accreditation and certification became mandatory, that at least at the time, did not affect access. Does anybody have any thoughts on with the number of units out there whether 3,000 or 5,000 if a percentage dropped out of the stereo business with federal regulation are we affecting access because I know this is always off the top of Congress's mind?

MEMBER MONTICCIOLO: That's a very good point. This is Dr. Monticciolo. I actually think there are more stereotactic tables than we need. Now I only say that because our table is not booked solid. And when we had an equipment problem, we actually had a power surge that blew the tube apart, luckily it happened at night, we had to shift our stereo patients to a satellite site and they were easily able to accommodate it.

It's very expensive equipment and in fact, I don't like to have it sitting still. So when a neighborhood hospital lost their stereo unit, we took their patients without any problem. Now that's just localized and it's very anecdotal obviously, but I can't imagine there are many

stereotactic units that are fully utilized morning to night. I would be surprised if that were the case.

CHAIR HENDRICKS: Thank you. Any other final comments about the IOM recommendations? Dr. Barr?

DR. BARR: No. Thank you.

CHAIR HENDRICKS: Thank you very much. It was very interesting. Thank you very much. So we'll move to the final item on our agenda this afternoon which relates to a discussion of recently issued guidance documents and other related topics to be led by Dr. Finder.

EXEC. SECRETARY FINDER: Okay. It's Dr. Finder. I want to go back to an issue that was brought up yesterday briefly and it deals with certification and an issue that is coming up before us very quickly. I want to frame the issue right now.

For those who aren't aware, one of our initial requirements for interpreting physicians is that they either be board certified or have two or

three months of training depending on when they qualified. Relatively recently, the board that we accept for interpreting physicians have begun issuing time-limited certificates. In the past, those certificates were issued for life. But starting in 2001 for one group, the Royal College of Physicians and Surgeons of Canada started issuing five year certificates and in 2002, the ABR, the American Board of Radiology and the American Osteopathic Board of Radiology started issuing ten year certificates.

The question that we have is in the past for all these years we've been looking at those certificates as a static being in the sense of once you got that certificate you had it. We didn't have to recheck it at all during the inspections.

The real question that we have now is should we in light of the fact that new people and this only applies to new people, the people who were issued certificates before these dates, their certificates are permanent, whether we should start inspecting against and checking these certificates

and we'd have to check them actually for everybody because we don't know who has a time-limited one and who doesn't have a time-limited one. So it becomes an issue of logistics and burden and paperwork and time. So I bring it before the committee to ask their opinion about should we basically accept the certificate once it's issued as permanent or should we go and start checking the expiration dates for all these certificates.

CHAIR HENDRICKS: I'll start the response. Carolyn Hendricks, Panel Chair. This is an issue that all hospitals are dealing with, all the health care systems, ABIM and I think that recertification should be required including documentation of recertification of the staff.

EXEC. SECRETARY FINDER: One other issue, one with a little caveat to this. As I said, our requirement is that you either be board certified or have the training. One of the situations that we could encounter, let's say, in five or ten years is somebody who was initially board certified, then decided not to take the board

certificate or failed the test or whatever it is at that time when then have to fall back on the other alternative which would be the two or three months of training. Actually, in this case, it would be the three months of training in mammography.

We have from past experience learned that the longer it is the time from your residency program the harder it is to get anybody to get documentation for you of what you actually did during your residency program. So we could have a situation where somebody goes out, is board certified, uses that certificate for proof of meeting that requirement, never get additional documentation about the three months of training in ten or twenty years. When their certificate expires and they don't renew it, we then go and ask them, "Now you have to show us that you've had three months of training ten or twenty years ago" and that is a problem or can be a problem.

CHAIR HENDRICKS: From the audience.

MR. MOURAD: Wally Mourad, FDA again. There is another issue that you should keep in mind

and that is for the initial qualifications of the interpreting physicians we equate the three months training with board certification. So if you got one or the other, you're good. You've met it.

Now if you start checking on the expired certificates, you're basically treating them differently from those who have acquired or provided the three months training because we don't recheck that. It's good for life.

MEMBER MONTICCIOLO: This is Dr. Monticciolo. That's a good point. I think it would be unfair to ask somebody to meet the higher standard of passing their board in radiology and then giving them a hard time ten years later when you've let somebody read who only had three months of training and didn't pass their boards.

But I also think we should check because I believe the current standard for board eligibility is, well, I guess you don't have to complete a residency training program but residency training programs not require three months of training in mammography. So I don't think we had any board

examiners sit who did not have that training. So if they initially passed their boards, I think they had to have had three months of training in residency. Maybe that's not true for people who are not passed repeatedly. I guess that's possible.

EXEC. SECRETARY FINDER: One would make the assumption that they have the three months of training. I will tell that for whatever reason in some specific instances we do have difficulty in people willing to sign that statement.

MEMBER MONTICCIOLO: I see. That's just information I lack.

EXEC. SECRETARY FINDER: But it really comes down to a question of how we should proceed on this question and it's going to be coming up actually next year because I don't know how many interpreting physicians we have who were certified by the Canadian board but their board is going up in 2006.

MEMBER FERGUSON: My thought would be that right now we accept the board certification and only since 2002 are the boards going to have to ten

years later go back. We have continuing education requirements. We have work requirements. I think once you're initially qualified, you're initially qualified would be my thought. You would hope everybody would go back and recertify but should that disqualify you for something that you've been doing very well for ten years, I don't think I would side there.

EXEC. SECRETARY FINDER: I will add, I want to make the topic more interesting, we have talked to some states and some of the states appear to have taken the stance that if you do not have an active, valid certificate they will not allow you to practice mammography. So some of the states at least are taking that stance at this point. They may be waiting for a lead from us to go in a different direction but we've heard back from some of the states and that's their position as of today.

MEMBER MONTICCIOLO: Could I ask a question about that? This is Dr. Monticciolo. So are you telling me there are states that are going to say the three months aren't good enough?

EXEC. SECRETARY FINDER: Correct. Some states actually have a requirement that you have to be board certified. They have a more stringent requirement than we do.

CHAIR HENDRICKS: Melissa.

MEMBER MARTIN: I guess my question is I would be really surprised why it would be acceptable for a radiologist not to renew their certification and still continue to do mammography when at that point they would not be allowed to do CT or MR or any other imaging modality. And maybe I'm missing something.

MEMBER MONTICCIOLO: First of all, you do not have to be board certified to read CT or any other modality. So that's not regulated at all and you can read CTs until the cows come without being board certified. But the issue I can see happening, Melissa, is what if you have a radiologist who is 59 years old or 60 and is very good reader and now he comes up against or she comes up against recerting and feels "I'm going to retire in three years. I'm not going to go through the recertification process

but I think I'm a good practitioner and I want to continue."

There's other reasons other than trying to sneak through the system that people may not want to recert. So we are going to come up against this I think.

EXEC. SECRETARY FINDER: I'm trying to get at least a feel for how the committee feels about this because again we have to make some decisions pretty quickly on this. So one alternative is to treat this as an initial requirement that never goes away that we would not look at again. The other is basically to say if you have a certificate that does expire, we're going to expect that certificate to be valid and current. So those are your basic two alternatives.

MEMBER MARTIN: And just to play Devil's advocate, I don't see, or I guess to play the other side of the coin, the inspection process treats the technologist as having to have current continuing education, current certification. So I guess if I'm playing the other side of things, I would think I

would expect the same thing of a radiologist that I would of the technologist and I don't see why the inspection procedure would be any different. The technologists already have to provide that documentation at every place they work and we expect that of the technologist.

So I can see where you could do it either way but it is required of all the technologist. At this point, you're setting a very different standard if you grandfather in and say you do not have to have a current qualification as the radiologist.

EXEC. SECRETARY FINDER: That is correct. We do require that the technologist show a current status on their certification. Again, I just want to throw in this point to make it more interesting. The American Board of Radiology is not only doing this to interpreting physicians. They are also doing it to medical physicists.

MEMBER MARTIN: Oh yes.

EXEC. SECRETARY FINDER: It is an issue that affect them too.

MEMBER MONTICCIOLO: While I appreciate the remarks Melissa has made, I agree with Dr. Ferguson. Right now, we're saying that somebody's is not board certified they are qualified to read mammography if they have three months of training. So it is setting a different standard if we force our board certified to recert and there is a continuing CME requirement. So I guess I would be in favor of allowing that to be the initial criteria for it and just leaving it at that.

CHAIR HENDRICKS: Carolyn Hendricks, Board Chair. I have a different take on it because I do agree that this is something all hospitals, all payers, are going to be scrutinizing. Every hospital in the United States does not know what to deal with their medical -- Every medical staff obviously in the country is dealing with this across all specialties. But the issue here might be to permit some grandfather process of the current population of interpreting physicians.

But I do think that we need to scrutinize the new interpreting physicians and set

maybe that higher standard and indicate that if they come in board certified that continuous board certification will be required because that's not the same as a 50 year old physician that's looking at one more year of active practice. This is the new generation of interpretative radiologists and we do want to set the bar quite high.

DR. BARR: Helen Barr, FDA. And, Dr. Hendricks, what you bring up certainly goes to what we've been talking about recruiting and retaining physicians in this field. Is this just one more thing if we change what is now an initial requirement to a continuing requirement? Are we just creating more problems for people entering and staying in our field?

CHAIR HENDRICKS: From the audience.

MR. MOURAD: Wally Mourad, FDA. I just want to comment on Melissa's point regarding the radiologic technologist. It's true that their board certification or state licensing if you will also has time limitations but it has been like this from day one and they're used to it. That's how they

always expected it. So there's no change for them. But this is a new requirement that affected basically the interpreting physicians and now possibly the medical physicists. So that's one different area.

MEMBER MARTIN: Melissa Martin. But I think it is a change that has happened in all aspects that these people are going to be practicing in. This is a change and it's a change that the ABR has made. So it's nothing different about maintaining current status to read mammography than it is the current status to practice the profession of either radiology or medical physics. The qualifications are the same and it's going to effect everybody and everything we do.

MEMBER MONTICCIOLO: I was just going to say we still have that initial requirements allow you to read if you have three months training and are not board certified. So you still have that. Why would you take somebody who met the higher standard and then penalize them by constantly looking at them? They can just fall back on the

three months if they can get the documentation. So what we are doing there?

MS. WILCOX: Pam Wilcox, ACR. Going back to the issue of the technologists, the techs on the panel can correct me if I'm wrong but it's my understanding you renew your certificate as long as you have your CEUs. But you don't have to take another exam. We're talking about for the radiologists and the physicists is reexamination. It's more comparable to their medical license as opposed to the board certification.

CHAIR HENDRICKS: Carolyn Hendricks, Board Chair. What is ACR's position on this dilemma of the physicians whose board certification is expiring?

MS. WILCOX: We have not taken a position. The ACR has not taken a position on this. One of the requirements for membership in the ACR is board certification. So we have a committee that will be looking at what position we're going to take.

EXEC. SECRETARY FINDER: All right.

Next, I wanted to address some guidance documents and one of the public comments that we heard in the morning dealt with the issue of our guidance document and how it deals with full field digital mammography. I think the issue is extremely important because some of the guidance that we put out will have a big effect on the future use of digital mammography.

Just to refresh everybody's memory, the first comment from Dr. Murray Reicher this morning was related to Guidance Document No. 9 which you all have. It's page 15 and according to him, it's question no. 5. Unfortunately because of the difference in printers, we don't have the exact same marker but I believe that what he was talking about was question no. 5 on page 14 on the versions that you have. Let's see what he talks about. He talks about -- Maybe 13.

(Discussion off microphone.)

EXEC. SECRETARY FINDER: Right. Fourteen is No. 5. Let's look at page no. 14, question no. 5. That's a charge one. So that's not

it.

(Discussion off microphone.)

EXEC. SECRETARY FINDER: Let's go through one of his topics though. Basically it's a question of can a facility, and this is on page 13, question no. 5, copy or digitize a film screen mammography and use that copy or digitized image for retentional final interpretation? The guidance that we put out is no for the reason that's listed there. And his comment basically is he wants to be able to show or making the claim that he can show that digitized or copied films can be used for final interpretation and should be allowed for final retention purposes.

This is a question that was brought up before the committee last time and we just want to bring it up again because it is so important and to get your feeling on this business about copying original mammograms and then discarding that original and just keeping the digitized image. Any comment?

MEMBER PURA: What happens to the

digitized?

EXEC. SECRETARY FINDER: I identify yourself.

MEMBER PURA: I'm sorry. Linda Pura. What happens to that because I'm not familiar with the process? What happens to that digitized film when you say you go to reproduce it? Is it a good production?

EXEC. SECRETARY FINDER: That's the entire issue.

MEMBER PURA: Yet I don't know.

EXEC. SECRETARY FINDER: Let me give some background.

MEMBER PURA: Because I haven't seen any of those done. So I would like to know what the comments are.

EXEC. SECRETARY FINDER: With film screen mammograms before full field digital came along, the statute and the regulations specifically precluded the use of copying of films. And the reason behind that was is the feeling was is that no matter how you tried to copy that film it would

never be the same as the original and we had huge problems with facilities that were being sent copies for comparison purposes or for biopsy purposes being sent films that they felt were of suboptimal quality. So in the regulations we were very strict about it and said that when the patient requests her examination that the originals be released.

With the advent of full field digital mammography, there is now a question of what is the original mammogram. How do you display it? How do you transport it? How do you retain it? With that, now comes the issue of can I take a film screen mammogram and put it in a digitizer, scan it in, and take that digital data and use that for various purposes and then he's asking discard the original. It makes it easier to store in some cases, easier to retrieve, certainly easier to send them to other facilities.

So there is a functionality that is gained by digitizing these film screen mammograms. The question is should we allow this process and under what conditions and under the guidance that is

currently out there, we have given basically a blanket no to it for the reasons we've stated here. The question is does anybody on this committee have any comments about that.

MEMBER MONTICCIOLO: Debbie Monticciolo. I'm not sure how good the digitizers are that this person who asked the question is talking about but I've never seen a digitized film screen product that was as good as the film screen image itself. There's going to be image loss. It's different if it's an acquired digital image and then you're talking about printing it out. That's a whole different issue.

But if you take a film screen mammogram and run it through a digitizer, you're going to lose information. I've never seen one that didn't lose some information. So I would think it would not be a good idea to destroy an original film that was taken with film screen because you're never going to be able to duplicate that just like you can't copy well. That's why they don't copy well. I've tried to scan in an awful lot of mammograms because I

lecture and I try to make images that look just like the film and it's a horrendous problem. You just lose detail.

MEMBER WILLIAMS: This is Mark Williams. I was going to say exactly the same thing and I don't know many research studies that use digitized film or copied films for that very reason. There's always some loss in those processes and the original film is always insisted upon. I don't see why it should be any different for patient care.

MEMBER FERGUSON: I was actually going to say what David did and I saw Mark's hand up and I was afraid he was going to stump us with a physicist's answer. I agree. I've never seen a film of any type digitalized that is as good as the original film.

EXEC. SECRETARY FINDER: My next question or actually his next question is what would it take you to convince you that you're wrong.

MEMBER WILLIAMS: Mark Williams. I guess a big reader study.

EXEC. SECRETARY FINDER: Okay. So

that's what you would recommend that before we would do something like this that a significant size reader study be done and would you be looking at end result or would you be looking at comparison of films because there are two different standards in one sense. You may be able to get the same diagnosis but still recognize that the film isn't the same and that you've lost something. So which one of those two standards do you think you would need or both?

MEMBER WILLIAMS: Mark Williams. If you set up the study so that you were just looking at correct diagnosis of images where there was a known lesion, then I'm not sure you would get the answer you wanted.

MEMBER MONTICCIOLO: Could I comment? It's Dr. Monticciolo. I don't think you would because once you know something's there or certain lesions would stand out regardless of if the film is diminished in quality. I know that because we often get copied films from older years from other facilities and I can use those minimally but you

really can't that film screen that's acquired the way it is and digitize it without losing something.

Now the question is is that something important. Isn't the modulation transfer function known for these devices or not? That's a physics question as you could tell. I'm amazed I can say that. MTF, modulation transfer function.

MEMBER WILLIAMS: This is Mark Williams and I think the answer to that is that the modulation transfer function is certainly characterizable for these systems. So you could measure the MTF prior and after. In reality, I don't think that data is very well known or studied very broadly across manufacturers simply because it's not a really straightforward, easy measurement to make like if you had a digitally acquired mammogram.

MEMBER MONTICCIOLO: Can I make one last comment? Sorry. We're going to be here all day if I keep this up. This is Dr. Monticciolo. I would just say even if we did a study we'd have to do a pretty large users' study to convince me that

there's a good reason to throw out an original film.

MEMBER HOLLAND: Jackie Holland. I'm thinking the same thing and I'm wondering from a legal standpoint and especially when you're looking at from the patient's angle to get rid of anything that was the original, what kind of problem are you going to have standing in a court of law? I just don't see that that's going to be possible.

EXEC. SECRETARY FINDER: Now as I say, I keep trying to make things more interesting. That's digitization of a film screen mammogram. Now we go to the next real issue that he brought up which is suppose you take a full field digital mammogram and compress the data and we in our guidance basically have said that we will accept the original data as the original or if it is compressed using a lossless compression algorithm such that when you regenerate that data it brings back the full data. We will accept that as the original.

His feeling in his statement was that he can compress using lossy compression, so there will some loss of data, fairly large amounts of

compression and he is using a term about visually lossless so that in some manner to the eye. And I tried to get him to pin this down through other correspondence but really wasn't able to get a firm definition of what he meant. But the general concept here is that if you looked at the image, you would not be able to see a difference. He's saying that if you can establish that why wouldn't you allow that type of compression?

MEMBER HOLLAND: Jackie Holland. I think though as Mark Williams there would have to be some kind of study done for me to accept that.

MEMBER MONTICCIOLO: Debbie Monticciolo. This is a slightly different issue is that there are images that have more information than the, I don't know how to say this except than to say that the eye can detect. Let me give you an example and maybe Dr. Williams can help me with this.

When I do slide presentations, I acquire the images of very high resolution but the projector can only project so much information. So what I do to make my talk smaller is I compress them and

there's no change in the image. The image looks identical to me and believe me, I'm really picky about my images. So if there were a change, I wouldn't accept it.

But you can go down to a resolution that's what can be projected and you can't detect the difference between a 50 megabyte image and 5. So if they could prove they were doing that, I really wouldn't have a problem with it. The question is how to prove that. It really would have to be completely apparent because I really wouldn't want to take a chance with losing pertinent information.

MEMBER WILLIAMS: This is Mark Williams. The other thing that complicates it is that different compression algorithms produce different results. When you uncompress the image, bring it back, then they have different tendencies to produce degradations. Some of them result in visible artifacts and it may be that a visible change equates to being able to see little isolated artifacts. That's very different than of a more

smooth but nevertheless very nonnegligible loss of image quality.

MEMBER MONTICCIOLO: I guess my opinion at this point would be unless there's information to the contrary I would not allow someone to use lossy technology. It would have to be lossless.

EXEC. SECRETARY FINDER: Okay. That's what the guidance says right now. He's coming back and saying what do I have to prove to you to get you to change your mind.

MEMBER WILLIAMS: Mark Williams. The other thing that I would add to the discussion is that I'm on another committee right now that's looking at the question of just image quality and digital mammography all together and one of the things that we did was an analysis of the pros and cons of various degrees of compression and one of the conclusions that popped up very quickly is that from an image storage standpoint there really aren't very strong arguments anymore like there originally were when digital mammography came about from the standpoint of space. Storage space is relatively

inexpensive and the only arguments, the strong arguments, for compression such as they are now would be in transmission. So I think that we should keep that in mind that some of the original impetus for trying to somehow make this work are not quite as strong anymore.

EXEC. SECRETARY FINDER: So you would say no.

CHAIR HENDRICKS: Carolyn Hendricks, Panel Chair. Just a comment. So then do we go to the vendor and mandate that? How will you be able to move forward if you don't have good clinical or technical data right now and this individual physician may not be able to create a dataset that is acceptable to change this guidance? Go back to the vendor? What steps could be taken to try to resolve this issue?

EXEC. SECRETARY FINDER: That's a very good question. This is not just a physician. This is the chair of a company who is actually interested in this.

CHAIR HENDRICKS: The vendor.

EXEC. SECRETARY FINDER: As it stands right now under our current guidance, and this is draft, we're waiting for other public comments, if this goes into effect, some of the things that he wishes to do would not be allowed. Part of his question though is what would it take to get people to see it his way and provide the proof that he feels he already intrinsically believes.

I guess that's a question that I'm hearing would require a clinical trial of some kind but even there the parameters of that clinical trial would have to be fairly well established in order to make sure that we're talking about the same thing. I will just for Devil's advocate talk about some of the other issues that were brought up by this person.

With certain full field digital detectors, there's actually more data than can be presented on the monitor. So while right now, the standard is that use of five megapixel, five million pixel, monitors depending on the machine you're using you may actually have more data than can

actually be presented on that screen. What he's basically saying is if you can't see it in the first place, why are you requiring me to store it and use it and keep it when I didn't make the diagnosis using that data to begin with? These are the types of questions that are being raised and they raise certain good issues. Go ahead.

MEMBER WILLIAMS: Mark Williams. I think the simplistic answer to that is that radiologists can use that information. They may not be able to visualize the entire mammogram in one view but if you zoom and roam, you certainly can get down to the level at which the image was originally acquired. So I don't think that necessarily the argument that you can't see it all in one view is grounds for throwing away information.

EXEC. SECRETARY FINDER: Okay. Very good. Part of his other question is right now the standard or the de facto standard for monitors is the use of the five megapixel monitor. One of his questions deals with the fact of why can't I use a lower resolution monitor and do exactly what you

just said, basically roam and scan over the image and look at the entire image at three megapixels and then scan each component of it at the full resolution. Do you have any comments about that?

MEMBER WILLIAMS: This is Mark Williams. I really think that's a question for the radiologists because the problem that you get if you have a smaller monitor with fewer pixels is that you have a lot more manipulation to do and so I think the tradeoff is going to be in through-put and ease of use.

MEMBER FERGUSON: I was just telling her you're just not going to do it. It's just not going to happen.

EXEC. SECRETARY FINDER: Well, never say never. Part of the rationale behind this is that a lot of facilities are going fully digital and while the monitors and the program setup for full field digital may have a five megapixel monitor, all the other monitors in the department may be of three or two or four, whatever, megapixel capabilities.

What one of his arguments is that in

order to make this process smoother, make the adoption of full field digital easier and less expensive is instead of having to view these on five megapixel monitors allow them to go through PACS systems and be viewed on three megapixel or other lower resolution monitors and then do the scanning of the full image at full resolution. Part of the issue that comes up is yes, this may take a little bit longer but there is a savings then. The decrease in efficiency may be made up for in the lower price that you would pay.

I will tell you that in our guidance because of the authorities that we have and the authorities we don't have we have actually said that while we recommend that you use the monitors specified by the FFDM manufacturer, we do not have the authority to require it and that as long as the monitor you use meets the quality control procedures as recommended by the FFDM manufacturer we cannot stop you from using that monitor. So if you as an end-user want to use a lower resolution monitor, we cannot stop that.

We can at this point tell a manufacturer that they can't advertise and sell a lower resolution monitor at the present time for that purpose. But as an end-user because of practice of medicine issues and our current limitations of regulatory authority, an end-user can use a lower resolution monitor. So that's part of the argument that he makes is you're allowing it under that circumstance. Why are you preventing these other activities such as digitization and lossy compression? So it's a very complicated issue and that's why I bring it up for the physicists.

MEMBER WILLIAMS: This is Mark Williams. I think that of the, I could be wrong on this, current FFDM units out there I think there may only be one where you can view the image at full resolution even on a 2.0 X 2.5 K monitor and that's just because the matrix size of the detectors is just larger than that. So I guess that means there's nothing really magic about 2.0 X 2.5 K. It's just that's reasonably affordable and out there.

EXEC. SECRETARY FINDER: Let me just for other people around here. A 2.0 X 2.5 K monitor is a five megapixel monitor.

MEMBER WILLIAMS: Right. But I think maybe I gave the impression in what I said a minute ago that it's a continuously sliding scale and if you had a two or four pixel monitor and you wanted to take enough time, you could read a mammogram. I think, and I would like to get the comments from the folks here, that many radiologists also like to have a sort of gestalt where they do see the whole mammogram at some acceptable level to compare it with a left/right or a current prior. And then you have to draw the line someplace although right now, I don't think we know exactly where that is.

MEMBER MARTIN: Okay. Melissa Martin and I'm going to put my two cents in. Everything Mark has said I would agree with and I guess from what I have seen and just watching the way the radiologists are reading, and obviously we have the two radiologists can speak up here at the end, the comment I consistently get at this point already is

the digital acquisition is much faster for the technologist and it is already "slower" for the radiologist.

We were in a group or we've been with a couple of groups and one of the radiologists blatantly made the statement "If it takes me more than 45 seconds to read an image, I'm losing money." I think Dr. Ferguson was right. The idea that they're going to scan and pan and spend five minutes looking at every image is not reality. But they're basically going to be doing is reading that image in a much lower resolution. So at this point, I have a real difficult time saying decrease the monitor resolution because most radiologists from what I've seen want to see that overall picture and then scan in on it.

MEMBER FERGUSON: I agree.

MEMBER MONTICCIOLO: It's Dr. Monticciolo. I think what Dr. Williams said was right that I don't think we know how it would affect the image quality to look at a four versus five monitor. But Dr. Finder is also right that there is

a significant barrier to entering into the digital realm because of the cost of the monitors. They're extremely expensive and that's one of the reasons my administrator is just loathed to do that. My experience with digital is from Massachusetts General but I think you really have to see it.

Every radiologist I think needs to get a gestalt just like Dr. Ferguson said, but I don't know what effect of a four versus a three versus a two. I just don't know where it is I would want to stop. I certainly would like the highest resolution possible. That would be the best of all worlds but that is a complicated issue because that is a huge expense for the system.

MEMBER MARTIN: Dr. Finder. I'm Melissa Martin. The other thing I would just add is the comment at least I'm hearing consistently for the radiologist we are in there using the digital systems of biopsy. They are using the monitor that is in the acquisition mode or in the room that the technologist usually uses which is a lower resolution monitor and it is not infrequent that I

get complaints that they cannot see on that monitor what they see on their review workstation which is the 5.0 K workstation. So several times, they've had to walk down the hall, look at the image on the 5.0 K workstation and then come back in. It's like "Oh, yeah. Now I can see on the lower resolution monitor because I know where to look."

In fact, I thought the request was almost going to go the other way. For those that are doing biopsies, they wanted the 5.0 monitors on the acquisition station so that they had the same resolution in the acquisition station if they're going to use it for biopsy procedures. At that point, I've heard it several times that there is a very different perception looking at that low resolution monitor.

MEMBER MONTICCIOLO: What's the resolution of the acquisition monitor?

MEMBER MARTIN: Is it a 2.0 K? The vendors would know more than I do. One K?

PARTICIPANT: One meg.

MEMBER MARTIN: I mean not 1.0 K, 1.0

meg.

MEMBER MONTICCIOLO: That's a pretty significant difference, isn't it?

MEMBER MARTIN: One or two depending on the vendor. So it's a significant difference. But if that's what we're talking about doing, I do know it is definitely a noticeable difference between the acquisition monitor and the review monitor.

MEMBER MONTICCIOLO: This is Dr. Monticciolo. I don't think anybody would want to go down to a one, but I don't know if there's a huge difference between five and four. I think we don't know. Certainly, if there is, then I would want to stay with the five but I don't think we have enough information to know that.

EXEC. SECRETARY FINDER: Okay. That makes me feel good. Next question that came up should be little easier and it deals with the use of cushion pads so that you don't have to worry about all this mathematical stuff. Basically for those people who are not familiar with it, there are some pads that are available that can be placed either on

the Bucky or on the compression paddle itself or both and they're used to minimize the discomfort from the compression during the mammographic procedure.

We have recently heard and I want to try and find out if this is anybody else's experience that the use of these pads may under certain circumstances cause a certain type of artifact. I just want to know if anybody's heard about this. I did ask this question before the committee met. I sent it out to them to see if they or any of their colleagues were aware of this type of artifact being produced.

MEMBER MARTIN: Melissa Martin. I did part of the original testing on these and that's why I'm looking. What kind of artifact are we looking for because I didn't find any at least from the physics mode? But that's not a clinical question. So is it an artifact that's showing up clinically?

EXEC. SECRETARY FINDER: Yes, it's an artifact that's been reported to show up during clinical examinations of patients with fatty breasts

where they're using high speed film cassette combinations or with FFDM, full field digital machines. And I'm not sure again what the cause of this is and I'm trying to get some information from people if anybody's heard of it.

MEMBER RINELLA: Diane Rinella. A couple different things here. I don't really remember quite when the pad came out. Maybe it was 2000, something like that. 1999. I was a supervisor of a prominent breast imaging center in California at the time and I tested the pad myself before allowing it to be utilized on our patients if they chose to use it.

And I was always under the foundation and taught and positioning in mammography that we always want the best as close to the image receptor as possible. Even though the pad may be just this thick, to me it was against everything that I worked so hard to try to do and that is to try to get as much information on the receptor detector as possible. So right there and the fact that it was raised bother me when I used it.

The second issue with the pad is that they provide two pads, one for the bottom and one for the top. And the one for the top covers the actual compression plate from underneath. So if you were use the top pad on the compression plate and bring that plate down, you are no longer able to see your breast basically. It covers the whole area. So you can't see as far as positioning is concerned, if your nipple is tracking straight, if you have lymph nodes that you've pulled over that you're trying to make sure you have the axillary area on or if you have any skin folds.

So the only way to really use the pad at that point was to only use it on the bottom. And in using it for myself, I found that because I tested it on my own body that the only thing that it provided for me, it wasn't more comfort, but that it provided warmth on the plate and that was basically it. There was a very slight, and I don't remember because this was a long time ago, increase in dose. So I thought at that point I'm not going to allow this to be used at my facility and I did not.

So I have not had any experience with it myself since that time. But in my travels throughout, I hear from technologists that are using digital equipment that they are seeing artifacts when they use the pad. So they have stopped. They haven't told me what specifically but they said that they are seeing artifacts.

MEMBER MONTICCIOLO: Dr. Monticciolo. I just wanted to ask a question. When this was originally approved for use, I'm assuming that digital wasn't in use at the time. So we probably don't have that data. But didn't the company have to provide data showing that it doesn't interfere with the image to get approved? And what data do we have? I don't know.

MEMBER MARTIN: But it was tested basically on a standard film screen system, not the ultra fast film screen systems and it certainly wasn't digital. That's why I was asking the details of why is it showing up. And that does make sense that if you're going to see it that's where you would see it. The original breast standard Kodak or

Fuji film system, it was not showing up and the dose difference was certainly less than one percent. So at that time, it was not a problem. I think you have a different set of parameters now and it would be a clinical based decision. If it's giving you artifacts, obviously you wouldn't use it.

MEMBER MOUNT: Carol Mount. I agree with Diane. When the pad first came out, I too was not in favor of it and we used it very sparingly. However we do use it on patients that are very apprehensive. It might just get them to have a mammogram. We would rather that they have a mammogram than not. So we will use the pad on the bottom. Putting it on the top does also as Diane said cause a problem because you end up repeating films because you can't see where the breast is on the receptor.

We've used them ever since they came out again sparingly with film and the only time we see an artifact is when it's misaligned and you can see the line of the edge of the pad because there's a difference in density. On our digital unit, we are

not seeing an artifact and we are using the pad.

EXEC. SECRETARY FINDER: Thank you for that information. Does anybody have any comments or questions about the guidance document especially no. 9? Guidance document no. 11 deals only with one topic and that is an issue that we discussed actually earlier and it deals with the fact that we will not be enforcing the requirement for continuing education in each specific mammographic modality and is consistent with our earlier discussions about the IOM recommendations.

The reason we put it out as a guidance document at this point was that since the requirement went into effect in 2002 we have continually been delaying implementation of this. We went from 2002 to 2004 to 2006 and 2006 was coming up quickly and people were starting to ask us questions and now with this advice that we've gotten from earlier advisory committees as well as the IOM, we put out a guidance document that said that we would indefinitely delay enforcement of that specific regulation. So that's document no. 11.

That leaves us again with any comments or questions about no. 9 if anybody had any. I surprised somebody hasn't asked me about where is document no. 10. Okay. So there are no other comments, questions or anything. It's good to go, document no. 9. Everybody thinks it's fine as is. Okay. Good. Thank you.

CHAIR HENDRICKS: Any other discussion related to guidance or any other issues?

EXEC. SECRETARY FINDER: Let me just check one thing.

CHAIR HENDRICKS: We have one item of business for our advisory committee and that is to say goodbye to four current members who will be departing from the panel after serving four years.

EXEC. SECRETARY FINDER: I do want to extend my personal thanks and also the thanks of the Food and Drug Administration to the following people who have served on the committee: Alisa Gilbert, Melissa Martin, Linda Pura and Miles Harrison who is on by phone. Their terms will end on January 31, 2006 and I doubt that we're going to have another

meeting before then. So I did want to extend my thanks to all those people for all the effort and the years that they put into this committee and the advice that they've given us which has been very helpful.

While you'll still be officially committee members till January 31th, chances are we will not be having another meeting before then. I wanted to say goodbye to you and wish you luck and it's been a pleasure having you on the committee. Thank you.

CHAIR HENDRICKS: And with that, barring any other business to discuss --

EXEC. SECRETARY FINDER: No. Can't leave just yet. Summary minutes. Do we have any summary minutes? Those of you who have seen the summary minutes from last meeting, does anybody have any comment on those minutes? Okay. I will take it that there were no comments to the summary minutes for the previous meeting.

CHAIR HENDRICKS: And with that, unless any panel members or members of the audience have

any other comments that they would like to submit to the record, we thank everyone for their participation and this meeting is adjourned. Off the record.

(Whereupon, at 3:08 p.m., the above-entitled matter concluded.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: National Mammography Quality Assurance Advisory Committee

Before: DHHS/PHS/FDA/CDRH

Date: September 27, 2005

Place: Gaithersburg, MD

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.